UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

Revised Review, July 6, 2011

MEMORANDUM

Subject: Efficacy Review for PeraClean 5 (Peroxyacetic Acid Solution), EPA Reg. No. 54289-3; DP Barcode: 387210

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7/6/11

To: Marshall Swindell PM33/ Martha Terry
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Applicant: Evonik Degussa Corporation
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Formulation from the Label:

Active Ingredient(s)	% by wt.
Hydrogen Peroxide	26.5%
Peroxyacetic Acid	4.9%
Other Ingredients	68.6%
Total	100.0%

I BACKGROUND

The product, PERACLEAN 5 (EPA Reg. No. 54289-3), is an EPA-approved disinfectant (bactericide, fungicide) and sanitizer for use on hard, non-porous surfaces in commercial, industrial, food preparation, and animal care environments. The applicant requested to amend the registration of this product to add new claims for effectiveness as a food contact sanitizer against *Salmonella typhimurium* and *Pseudomonas aeruginosa*. The label states that the product is effective as a sanitizer in water of up to 400 ppm hardness as $CaCO_3$. According to the registrant letter (dated February 2, 2011), "Evonik Degussa received notice that [this] product is not efficacious when tested as a hospital disinfectant against *Pseudomonas aeruginosa* (ATCC 15442). We would like to remove this claim from the label along will all references to use in healthcare facilities at this time" (registrant's enclosed letter). A revised review was provided to address the use rate discrepancies. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121; and MICROBIOTEST, located at 105 Carpenter Drive in Sterling, VA 20164.

This data package contained a letter from the applicant to EPA (dated February 2, 2011), two studies (MRID 483753-01 and 483753-02), Statements of No Data Confidentiality Claims for both studies, and the proposed label.

II USE DIRECTIONS

The product is designed for sanitizing hard, non-porous surfaces, including: equipment, pipelines, tanks, vats, fillers, evaporators, and pasteurizers. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: glass, glazed porcelain, linoleum, plastic (e.g., polyethylene, polypropylene), stainless steel, and vinyl. Directions on the proposed label provide the following information regarding preparation and use of the product as a sanitizing rinse on food contact surfaces: Prior to sanitizing, remove gross food particles. Wash with a detergent solution, followed by a potable water rinse. Prepare a use solution by adding 1.0 to 1.5 ounces of the product and 5 gallons of water (a 1:427 to 1:640 dilution). For treating against *Pseudomonas aeruginosa*, prepare a use solution by adding 2.1 to 2.3 ounces of the product and 5 gallons of water (a 1:278 to 1:305 dilution). Use immersion, coarse spray, or circulation technique as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for at least 60 seconds or more if specified by the governing sanitary code. Drain thoroughly and allow to air dry. Do not rinse.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces; Additional Bacteria)

There are cases where an applicant requests to make claims of effectiveness against additional bacteria for a product that is already registered as a sanitizing rinse for previously cleaned, food contact surfaces. EPA staff indicated that the DIS/TSS-5 standards are silent on this matter and that confirmatory test standards would apply. EPA staff indicated that, for sanitizing rinses for previously cleaned, food contact surfaces, 2 product samples, representing 2 different product lots, must be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.999% in the number of microorganisms within 30 seconds. The results must be

reported according to the actual count and the percentage reduction over the control. Furthermore, according to information in the above AOAC test method itself, counts on number controls for the product should fall between 75 and 125 x 10^6/mL for percent reductions to be considered valid. Label directions for use, however, must state that a contact time of at least 1 minute is required for sanitization.

Supplemental Claims

On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 483753-01 "Germicidal and Detergent Sanitizing Action of Disinfectants," Test Organism: *Pseudomonas aeruginosa* (ATCC 15442), for PERACLEAN 5, by Nadia A. Hashimee. Study conducted at MICROBIOTEST. Study completion date – August 20, 2010. Laboratory Project Identification Number 529-108.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. 8250062101, 8250062401, and 8250050602) of the product, PERACLEAN 5, were tested. The laboratory report referenced the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. At least one of the product lots tested (i.e., Lot No. 8250050602) was at least 60 days old at the time of testing. Use solutions were prepared by adding 0.32 mL of the product and 99 mL of 400±2.9% ppm AOAC synthetic hard water (a 1:309 dilution). A culture of the challenge microorganism was prepared in accordance with the published AOAC method, with the following exception: 2 mL of phosphate buffer dilution water and sterile glass beads were used to suspend growth (which differs from the AOAC method specification of using 3 mL phosphate buffer dilution water and glass beads). Standardization information was not provided. [The AOAC method states to standardize the culture to give an average of 10 x 10^9 organisms/mL.] Use solutions were not tested in the presence of a 5% organic soil load. Two replicates per product lot were tested. A 99-mL aliquot of each use solution was transferred to a 250 mL Erlenmeyer flask and placed in a water bath at 25°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to tubes containing D/E Neutralizing Broth exactly 30 and 60 seconds after the addition of the bacterial suspension. Neutralizer tubes were mixed thoroughly and serially diluted in phosphate buffer dilution water. Selected aliquots were plated in tryptone glucose extract agar. All plates were incubated for 48±2 hours at 37±2°C. Following incubation, the colonies were counted. Controls included those for numbers count, sterility, neutralizer effectiveness, and confirmation of the challenge microorganism.

Note: Protocol deviations/amendments reported in the study were observed.

2. MRID 483753-02 "Germicidal and Detergent Sanitizing Action of Disinfectants," Test Organisms: *Listeria monocytogenes* (ATCC 19111) and *Salmonella typhimurium* (ATCC 23564), for PERACLEAN 5, by Amy S. Jeske. Study conducted at ATS Labs. Study completion date – November 15, 2006. Project Number A04059.

Testing against *Listeria monocytogenes* was cancelled per the Sponsor's request.

This study was conducted against *Salmonella typhimurium* (ATCC 23564). Two lots (Lot Nos. 129PAR7201 and 129PAS6323) of the product, PERACLEAN 5, were tested. The laboratory report referenced the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method (modified) as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. At least one of the product lots tested (i.e., Lot No. 129PAR7201) was at least 60 days old at the time of testing. Use solutions were prepared by adding 1.62 mL of the product and 1.0 L of 400 ppm AOAC synthetic hard water (titrated at 395-399 ppm; a 1:617 dilution) and by adding 1.93 mL of the product and 1.0 L of 400 ppm AOAC synthetic hard water (titrated at 395-399 ppm; a 1:518 dilution). A culture of the test organism was prepared in accordance with the published AOAC method. The inoculum matched a 4.0 McFarland Turbidity Standard. Use solutions were not tested in the presence of a 5% organic soil load. Two replicates per product lot were tested. A 99.0-mL aliquot of each use solution was transferred to a 250 mL Erlenmeyer flask and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Letheen Broth with 0.07% Lecithin, 0.5% Tween 80, and 0.1% sodium thiosulfate exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 48±4 hours at 35-37°C. The plates were stored for 2 days at 2-8°C prior to reading. Following incubation and storage, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

Note: The laboratory reported a failed study set up on July 13, 2006 against *Listeria monocytogenes*. In the study, the numbers control failed to meet the acceptance criterion of 75-125 x 10^6 CFU/mL. Testing was repeated on July 28, 2006. In the study, the numbers control also failed to meet the acceptance criterion of 75-125 x 10^6 CFU/mL. Testing was repeated on August 8, 2006. In the study, the numbers control also failed to meet the acceptance criterion of 75-125 x 10^6 CFU/mL. The laboratory did not accept any of the assays. These data were not used to evaluate efficacy of the product. Testing against *Listeria monocytogenes* was cancelled per the Sponsor's request. See pages 8 and 13 and Attachment I, II, and III of the laboratory report. [Note that for each of these studies, bacterial reductions of at least 99.999 percent over the parallel control were not observed within 30 seconds.]

V RESULTS

MRID Number	Organism	Lot No.	Average No. Surviving (CFU/carrier)	Microbes Initially Present (CFU/carrier)	Percent Reduction
30-Second Exposure Time					
483753-01	*Pseudomonas aeruginosa*	180 ppm 8250062101 8250062401 8250050602	 <5.0×10^0 <5.0×10^0 <5.0×10^0	 7.7×10^7 7.7×10^7 7.7×10^7	 >99.999 >99.999 >99.999
483753-02	*Salmonella typhimurium*	88 ppm: 129PAR7201 129PAS6323	 <1×10^1 <1×10^1	 1.24×10^8 1.24×10^8	 >99.999 >99.999
	Salmonella typhimurium	105 ppm 129PAR7201 129PAS6323	 <1×10^1 <1×10^1	 1.24×10^8 1.24×10^8	 >99.999 >99.999
60-Second Exposure Time					
483753-01	*Pseudomonas aeruginosa*	180 ppm 8250062101 8250062401 8250050602	 <5.0×10^0 <5.0×10^0 <5.0×10^0	 7.7×10^7 7.7×10^7 7.7×10^7	 >99.999 >99.999 >99.999

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, PERACLEAN 5, as a sanitizing rinse against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 400 ppm hard water for a 30-second contact time at the specified dilution:

Pseudomonas aeruginosa	MRID 483753-01
Salmonella typhimurium	MRID 483753-02

Bacterial reductions of at least 99.999 percent over the parallel control were observed within 30 seconds. At least one of the product lots tested was at least 60 days old at the time of testing. In studies against *Pseudomonas aeruginosa*, neutralizer effectiveness testing showed positive growth of the microorganism. In testing against *Salmonella typhimurium*, neutralization confirmation testing met the acceptance criterion of growth within 1 $\log_{10}$ of the numbers control. When reported, viability controls were positive for growth. When reported, purity controls were reported as pure. Sterility controls did not show growth. ATS Laboratory Protocol No. DEG01060506.GDST, referenced in the laboratory report, was not provided. This must be submitted to the Agency.

VII RECOMMENDATIONS

1. The proposed label claims that a 1:427 to 1:640 dilution of the product, PERACLEAN 5, is an effective sanitizing rinse against *Salmonella typhimurium* on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 400 ppm hard water for a 1-minute

contact time. This claim is acceptable. A rationale was provided to clarify the use rate discrepancies cited in the earlier efficacy review.

2. The proposed label claims that a 1:278 to 1:305 dilution of the product, PERACLEAN 5, is an effective sanitizing rinse against *Pseudomonas aeruginosa* on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 400 ppm hard water for a 1-minute contact time. This claim is acceptable as it is supported by the submitted data. A rationale was provided to clarify the use rate discrepancies cited in the earlier efficacy review.

3. Claims to support food contact sanitization uses as a foam must be supported by efficacy data. This data must be accepted by the Agency before this method of application can be approved. Until such time, foam sanitization claims are unacceptable.

4. The following revisions to the proposed label are recommended:

- Under the "Precautionary Statements" section of the proposed label, change "before eating, drinking, or using tobacco" to read "before eating, drinking, chewing gum, using tobacco, or using the toilet."

- Add ATCC numbers are required for all microorganisms in one of these locations,
  - on the data matrix;
  - the master label (as optional text) with the listing of the organisms claimed, or
  - As the final page of the master label (as optional text).

- Correct the spelling of "*Pseudomonas aeruginosa*."

- Change "*E. coli* 0157:H7" to "*E. coli* O157:H7."

- Change "*Salmonella choleraesuis*" to "*Salmonella enterica*"